No. 78-605

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UNITED STATES OF AMERICA, ET AL., PETITIONERS

v.

GLEN L. RUTHERFORD, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

REPLY BRIEF FOR THE UNITED STATES

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1. After the United States filed its main brief in this case, the Supreme Court of California issued its decision in *People* v. *Privitera,* Crim. No. 20340, Super. Ct. No. CR-32978 (Mar. 15, 1979). The court sustained, against a right-of-privacy challenge based on both the federal and the state Constitutions, the criminal convictions of four distributors of Laetrile and a physician who had prescribed the drug for cancer patients. The convictions had been obtained under sections of the California Health and Safety Code making it a misdemeanor to sell, deliver, prescribe, or administer any drug or device to be used in the diagnosis, treatment, or cure of cancer if the drug or de-

vice has not been approved either under Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355 ("the Act"), or by a designated state board. Cal. Health & Safety Code § 1707.1 (West 1970), § 1709 (West 1971–1978 Cum. Supp.) The court held that the defendants' "asserted right to obtain drugs of unproven efficacy is *not* encompassed by the right of privacy embodied in either the federal or the state Constitutions." *People* v. *Privitera, supra,* slip op. 4 (emphasis in original).[1]

2. Respondents attack (Br. 29–32) the decision by the Commissioner of Food and Drugs to conduct informal rulemaking proceedings to develop the record on which to make his determination regarding the status of Laetrile. Respondents claim that the use of such proceedings contravened the initial decision of the Tenth Circuit remanding the case to the Food and Drug Administration for development of an administrative record (A. 40–41), manifested a prejudgment of the issues, and improperly denied respondents a right of cross-examination. Since this case is before the Court on the government's petition, respondents' argument can be offered only as a basis for affirming the judgment of the court of appeals. The argument is not a logical ground for affirming that judgment, and in any event lacks merit.

[1] The California Supreme Court's decision reversed a lower court decision holding the convictions invalid on constitutional grounds. *People* v. *Privitera*, 141 Cal. Rptr. 764 (Ct. App. 1977). We are lodging with this Court copies of the California Supreme Court's decision (with dissenting opinions) in *Privitera*, and we are sending a copy to counsel for respondents.

The court of appeals, in its decision following the remand to the FDA, recognized the "difficulties in making a record when the proponents of a drug are a group of individuals and not the typical drug manufacturer who conducted extensive laboratory tests and assembled a mass of scientific data" (Pet. App. 4a). The court did not hold the Commissioner's proceeding improper, but accepted it as the basis for judicial review (see Pet. App. 5a). Respondents' attack on the proceeding, instead of providing a basis for sustaining the court's judgment, would presumably require a new remand to the Commissioner.

Moreover, the Commissioner's proceeding was entirely appropriate. It was designed to promote easy and effective public participation and to afford Laetrile proponents ample opportunity to submit data, express their views, comment on previously filed testimony, and ventilate all issues.[2] The lack of an opportunity to cross-examine witnesses—a matter respondents did not raise until May 2, 1977, the day of oral argument before the agency (Tr. 10)—did not prejudice respondents or preclude the making of an adequate record for the Commissioner's decision. The medi-

[2] Members of the public were invited to submit verified written statements on the "new drug" and grandfather clause issues. 42 Fed. Reg. 10066, 10068 (1977). Copies of all record submissions were made available for public inspection in cities throughout the country. *Id.* at 10069. An opportunity was provided to file verified written replies to filed submissions. *Id.* at 10068. Oral argument was held in Kansas City, Missouri, "a place of central location," in order to "permit broader public participation." *Id.* at 10069. Known Laetrile proponents were specifically invited to participate to the fullest extent in the proceeding. See *id.* at 39768.

cal and scientific questions confronting the Commissioner were not of such a nature that the cross-examination afforded in a more formal adjudicatory proceeding would have illumniated the search for truth. *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 700 (2d Cir. 1975); see also *Mathews* v. *Eldridge*, 424 U.S. 319, 344–345 (1976). In any event, an agency's choice of procedures for making decisions is, in the absence of statutory or constitutional constraints, a matter within its discretion and one not lightly to be seized on as a means of disturbing the agency's decision. *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.*, 435 U.S. 519, 524, 542–548 (1978). See also *United States* v. *Florida East Coast Ry.*, 410 U.S. 224 (1973).[3]

[3] Respondents argue (Br. 37) that the FDA improperly treated Laetrile as a new drug without first conducting an administrative proceeding. Administrative action of the type contemplated by the Administrative Procedure Act, 5 U.S.C. 553 and 554, or by section 701(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), is not a prerequisite to regulatory proceedings under the Federal Food, Drug, and Cosmetic Act. *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950). See also *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 146–148 (1967). The claimant to a drug seized pursuant to 21 U.S.C. 334 has a right to a judicial hearing, and an importer whose drug shipment is denied admission to this country under 21 U.S.C. 381(a) has a right to an administrative hearing with judicial review. In these proceedings the status of the drug may be determined. It is through such proceedings that the FDA is able to block distribution of unapproved "new drugs," and nothing in the applicable statutes or the Constitution requires the agency to make a formal administrative determination before invoking such proceedings.

3. In their attempt to establish that Laetrile was commercially used or sold in the United States on October 9, 1962, as required by the 1962 grandfather clause (Section 107(c)(4) of the Drug Amendments of 1962, Pub. L. No. 87–781, 76 Stat. 789), respondents note that "amygdalin" was listed in the Merck Index for 1907 and 1940 (Br. 36). Even if it is assumed, contrary to our submission (Main Br. 6–7, 41–43), that amygdalin and Laetrile are the same drug, the 1907 and 1940 volumes of the Merck Index do not prove that Laetrile was commercially available in 1962. Indeed, amygdalin was not listed in the Merck Index for 1952 or for 1960, the only editions published between 1940 and 1962. Moreover, amygdalin was never listed in the Merck Index as a finished pharmaceutical product to be used as a treatment for cancer. The 1940 edition, for instance, listed amygdalin as a powder, not a tablet or injectable drug, and described it as a "rarely" used substitute for hydrocyanic acid; the volume described hydrocyanic acid as a drug used in the treatment of "nervous, irritable coughs; in gastralgia of nervous origin, nervous vomiting, [and] gastric irritability." Merck Index 38, 276 (1940).

Respondents also attack (Br. 39–40) the Commissioner's legal conclusion that Laetrile is not exempt from classification as a new drug unless it is shown that it is currently " 'intended solely for use under conditions prescribed, recommended, or suggested' " in its 1962 labeling (Pet. App. 191a, quoting Section 107(c)(4) of the Drug Amendments of 1962, Pub. L.

No. 87–781, 76 Stat. 789), and that "conditions of use" include "what the drug is recommended for" (*ibid.*). Respondents call this a "legal error" (Br. 40) that would lead to such absurd results as the classification of aspirin as a new drug if anyone should promote it for any use for which it was not recommended in 1962 (*id.* at 39); and they contend that the proper rule is that Laetrile may escape new drug classification "*to the extent* that it is currently being used for the same purposes and under the same conditions as on October 9, 1926" (*id.* at 40; emphasis in original). Respondents' argument, like the reasoning of the district court on which it relies (Pet. App. 15a–16a n.7), overlooks the fact that, under Section 505 of the Act, 21 U.S.C. 355, drugs are licensed not in general but for marketing by specific individual manufacturers. Thus, in respondents' hypothetical case based on aspirin, only that firm whose aspirin was sold for a new and different use would lose its grandfather exemption and be required to secure premarketing approval for the drug. See *USV Pharmaceutical Corp.* v. *Weinberger,* 412 U.S. 655, 664 (1973). This result reflects sound public policy. Even a familiar drug should not be labeled and promoted for a new use without testing showing that it is effective for that use. Otherwise, patients could be led to forsake effective therapy in favor of ineffective therapy.[4]

[4] Respondents contend (Br. 23) that the record is "replete with evidence of the 'pain-killing' effect of Laetrile" which the Commissioner's opinion does not "rebut." Therefore, they contend (Br. 24), Laetrile comes within "the 'effective' classification of the Act as perceived by Senator Eastland," a supporter of the 1962 Drug Amendments that imposed an effectiveness requirement to be met by all new drugs before they can be approved for marketing. It is unclear whether respondents mean (1) that the proffered evidence of analgesic effect shows that the drug "will have the effect it purports or is represented to have" for its recommended use (21 U.S.C. 355(d)(5)) and therefore meets one of the requirements for approval of a new drug application, or (2) that Laetrile is "generally recognized" as "effective" for relief of cancer pain by "experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs" (21 U.S.C. 321(p)), and therefore meets one of the criteria for escaping classification as a new drug.

The answer to the first possible argument is that there was no new drug application for Laetrile pending before the Commissioner. The answer to the second possible argument is that the Commissioner applied the proper standards and made an appropriate decision in determining that Laetrile is not generally recognized as effective. Applying the relevant statutory standard as construed by this Court (see *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 652–653 (1973)), the Commissioner rejected as unreliable (Pet. App. 100a–101a, 234a–242a) the kind of evidence on which respondents primarily seek to rely-testimonials by patients and physicians—and gave weight to the testimony of those "qualified by scientific training and experience" (21 U.S.C. 321(p)(1)) to evaluate drug safety and effectiveness. Such experts evaluated claims that Laetrile has an analgesic effect (see *e.g.*, Pet. App. 99a–100a, 130a, 131a, 137a–138a, 139a–140a, 144a–145a). They explained that analgesic effects ascribed by some patients to Laetrile are apparently attributable to factors such as placebo reactions and coincidental cessation of therapies with uncomfortable side effects (*id.* at 99a–100a, 234a–242a). (Belief by some patients that Laetrile relieves pain is understandable in view of studies showing that more than 20 percent of cancer patients experience relief of pain when given an inert medication. Moertel, Ahmann, Taylor and Schwartau, *A Comparative Evaluation of Marketed Analgesic Drugs*, 286 N. Eng. J. Med. 813, 814 (1972).)

On the basis of the entire record, the Commissioner properly found that no adequate and well-controlled clinical investigations were submitted to show that Laetrile is effective for any purpose (Pet. App. 100a), and "that the overwhelming majority of experts in the evaluation of the safety and effectiveness of drugs do not

(Continued)

4. Respondents (Br. 48) and certain amici (*e.g.*, McNaughton Foundation Br. 10–11; Cancer Control Society Br. 5–6) point to the existence of some state laws permitting, in varying degrees, some form of Laetrile traffic and use within the states in question. They suggest that the existence of these laws demonstrates that Laetrile is a safe and effective alternative to accepted treatments for cancer, and therefore that the federal government can have no compelling public health interests in forbididng interstate distribution of the drug. These state laws do not, however, purport to represent scientific judgments that Laetrile is a safe and effective anti-cancer drug; indeed, the legislatures of some of these states have expressly stated that their law is not to be considered an endorsement of the drug's worth. See, *e.g.*, Ind. Code Ann. § 16–8–84–4 (Burns 1977 Cum. Supp.); Wash. Rev. Code § 70.54.130 (West 1977 Cum. Supp.). In any event, the willingness of some states to allow traffic in a drug does not establish that the agency entrusted by Congress with the task of regulating the distribution of drugs in interstate commerce may not properly find reasonable and even compelling reasons for barirng such distribution. Cf. Nightengale and Perry, *Marijuana and Heroin by Prescription?*, 241 JAMA 373 (1979).[5]

(Continued)
recognize Laetrile as effective" (*id.* at 154a). He accordingly concluded that Laetrile is not generally recognized as safe and effective "for any therapeutic use" (*id.* at 272a).

[5] Amicus the Cancer Control Society cites (Br. 7) John Stuart Mill's essay *On Liberty* (1859) for the proposition that the government has no legitimate interest in forbidding distribution of Laetrile absent proof of harm to persons other than those who choose to use it. Even assuming that the availability of Laetrile would involve no harm to the families of patients mistakenly diagnosed as terminally ill who might forego accepted therapy that could cure or retard their disease, we doubt that Mill's doctrine should be written into our Constitution as a restriction not only on the Federal Food, Drug, and Cosmetic Act, but on various other laws designed to promote the public health and safety. As one scholar has asked: "If the Constitution does not enact Herbert Spencer's *Social Statics*, does it enact John Stuart Mill's *On Liberty* (1859)?" P. Brest, *Processes of Constitutional Decisionmaking* 798 (1975). See also H. Hart, *Law, Liberty and Morality* 32–33 (1963); *e.g.*, *Roe* v. *Wade*, 410 U.S. 113, 154 (1973).

CONCLUSION

For the foregoing reasons, and for those set forth in our main brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

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